FORM PTO-1390 (REV 10-2000)

U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: Beiersdorf 704

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 09/744506

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP99/05157	July 20, 1999	August 1, 1998

TITLE OF INVENTION: COSMETIC AND DERMATOLOGICAL PREPARATIONS HAVING AN EFFECTIVE CONTENT OF BILE ACIDS, THEIR SALTS AND/OR THEIR DERIVATIVES

APPLICANT(S) FOR DO/EO/US: Ghita LANZENDORFER and Volker SCHREINER

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. [X] The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [X] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:

Copy of first page of PCT/EP99/05157 (WO 00/07557)

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
09/744506	PCT/EP99/05157	Beiersdorf 704

17. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1000.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**	
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$860.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	13 - 20 =	0	X **$18.00**	$ 0.00
Independent claims	2 - 3 =	0	X **$80.00**	$ 0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$270.00**	$

TOTAL OF ABOVE CALCULATIONS =	$860.00
[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.	$
SUBTOTAL =	$860.00
Processing fee of **$130.00** for furnishing the English translation later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492(f)). +	$
TOTAL NATIONAL FEE =	$860.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$
TOTAL FEES ENCLOSED =	$860.00
Amount to be refunded:	$
charged:	$

a. [ ] A check in the amount of $_____ to cover the above fees is enclosed.

b. [X] Please charge my Deposit Account No. 14-1263 in the amount of $860.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1263. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO.

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Victoria M. Malia
NAME

39,359
REGISTRATION NUMBER

Our Docket Number Beiersdorf 704

Client Docket Number 6713-Dr.Wi-hf

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	G. LANZENDÖRFER ET AL.
SERIAL NO.	:	*TO BE ASSIGNED*
FILED	:	JANUARY 24, 2001
FOR	:	COSMETIC AND DERMATOLOGICAL PREPARATIONS COMPRISING AN EFFECTIVE CONTENT OF BILE ACIDS, THEIR SALTS AND/OR THEIR DERIVATIVES
ART UNIT	:	*TO BE ASSIGNED*
EXAMINER	:	*TO BE ASSIGNED*

Date January 24, 2001

BOX PCT
Assistant Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Applicants submit the following Preliminary Amendment in order to place the instant application in better condition for examination on the merits.

IN THE CLAIMS:

Please cancel Claims 1 through 7 without prejudice.

Please insert the following new claims:

-- 8. (New) A cosmetic and/or dermatological preparation comprising an active ingredient selected from the group consisting of bile acids, salts of bile acids, derivatives of bile acids, and mixtures thereof. --

-- 9. (New) The preparation according to Claim 8, further comprising cosmetic or dermatological auxiliaries, additives, and/or other active ingredients. --

-- 10. (New) The preparation according to Claim 8, wherein the amount of the active ingredient is in the range of about 0.001 to about 10% by weight, based on the total weight of the preparation. --

-- 11. (New) The preparation according to Claim 10, wherein the amount of the active ingredient is in the range of about 0.01% to about 1% by weight, based on the total weight of the preparation. --

-- 12. (New) The preparation according to Claim 11, wherein the amount of the active ingredient is in the range of about 0.01% to about 0.5% by weight, based on the total weight of the preparation. --

-- 13. (New) The preparation according to Claim 8, wherein the active ingredient is selected from the group consisting of deoxycholic acid, ursodeoxycholic acid, taurocholic acid and salts and derivatives thereof. --

-- 14. (New) The preparation according to Claim 8, wherein the active ingredient is selected from the group consisting of esters of bile acids and ethers of bile acids. --

-- 15. (New) The preparation according to Claim 8, wherein the active ingredient is selected from the group consisting of alkali metal and alkaline earth metal salts, salts of mono- or divalent cations of elements from the transition groups, salts of mono- or divalent cations of elements from the lanthanides, salts of mono- or divalent cations of elements from the actinides, salts of ammonium ($-NH_3$), alkanolammonium derivatives having 2 to 9 carbon atoms in total, alkyl- and alkenylammonium derivatives having 1 to 22 carbon atoms in total, pyridine substituted by an alkyl or alkenyl group which has 1 to 18 carbon atoms, and salts of basic amino acids. --

-- 16. (New) The preparation according to Claim 8, wherein the preparation is in an encapsulated form. --

-- 17. (New) The preparation according to Claim 16, wherein the encapsulated form is selected from the group consisting of collagen matrices, cellulose encapsulations, gelatin, wax matrices, and liposomal encapsulations. --

-- 18. (New) The preparation according to Claim 16, wherein the preparation is in solution form. --

-- 19. (New) A method for strengthening the barrier function of the skin that comprises applying the preparation according to Claim 8 to the skin. --

-- 20. (New) A method for strengthening the barrier function of the skin that comprises applying a preparation comprising about 0.01% to about 0.5% by weight, based on the total weight of the preparation, of an active ingredient selected from the group consisting of deoxycholic acid, ursodeoxycholic acid, taurocholic acid, and salts and derivatives thereof to the skin. --

Our Docket Number Beiersdorf 704
Client Docket Number 6713-Dr.Wi-hf

REMARKS

Claims 1-7 are canceled. New claims 8-20 are added. Claims 8-20 are the only claims pending in the instant application and are presented for consideration.

The above amendments were necessary to eliminate multiple dependent claims and otherwise bring the instant application into conformance with accepted US patent application practice.

Applicants aver that no forbidden new matter has been added by the above amendments.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By Victoria M. Malia
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Express Mail Label Number: **EL 770070387 US**

Date of Deposit: **24 January 2001**

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Beiersdorf Aktiengesellschaft Hamburg

Description

Cosmetic and dermatological preparations having an effective content of bile acids, their salts and/or their derivatives

The present invention relates to cosmetic and dermatological preparations having an effective content of bile acids, their salts and/or their derivatives, and to the use thereof for strengthening the barrier function of the skin.

The skin is the largest human organ. Amongst its many functions (for example for temperature regulation and as a sensory organ) the barrier function, which prevents the skin (and thus ultimately the entire organism) from drying out, is probably the most important. At the same time, the skin acts as a protective device against the penetration and absorption of external substances. This barrier function is effected by the epidermis which, as the outermost layer, forms the actual protective sheath against the environment. Being about one tenth of the total thickness, it is also the thinnest layer of the skin.

The epidermis is a stratified tissue in which the outer layer, the horny layer (Stratum corium), is the part which is of significance for the barrier function. Being in contact with the environment, it is worn away and therefore finds itself in a continuous process of renewal, where, on the outside, fine flakes are continuously shed and, on the inside, keratinized cell and lipid material is subsequently produced.

The Elias skin model, which is currently recognized in the specialist field (*P. M. Elias, Structure and Function of the Stratum Corneum Permeability Barrier, Drug Dev. Res.* ***13,*** *1988, 97-105*), describes the horny layer as a two-component system, similar to a brick wall (bricks and mortar model). In this model, the horny cells (corneocytes) correspond to the bricks, and the lipid membrane, which is of complex composition, in the intercellular spaces corresponds to the mortar. This system essentially represents a physical barrier to hydrophilic substances, but, because of its narrow and multilayered structure, can equally,

however, also be passed by lipophilic substances only with difficulty. The particular structure of the horny layer on the one hand protects the skin and on the other hand stabilizes its own flexibility by binding a defined amount of water.

Mechanical stresses, such as, for example, compressive forces, impacts or shear forces, can also be intercepted to a surprising degree by the horny layer alone or in conjunction with the deeper layers of the skin. Relatively large compressive forces, torsional forces or shear forces are transmitted to deeper layers of the skin via the meshing of the epidermis with the corium.

The regulation of the water and moisture content is one of the most important functions of the epidermal lipid membrane. However, it not only has a barrier effect against external chemical and physical influences, but also contributes to the holding together of the horny layer.

The lipids of the horny layer essentially consist of ceramides, free fatty acids, cholesterol and cholesterol sulfate and are distributed over the entire horny layer. The composition of these lipids is of decisive importance for the intact function of the epidermal barrier and thus for the water impermeability of the skin.

Even cleansing the skin using a simple waterbath - without the addition of surfactants - initially causes the horny layer of the skin to swell. The degree of this swelling depends inter alia on the bathing time and temperature. At the same time, water-soluble substances are washed off or out, such as e.g. water-soluble constituents of dirt, but also substances endogenous to the skin which are responsible for the water-binding capacity of the horny layer. In addition, as a result of surface-active substances which are endogenous to the skin, fats in the skin are also dissolved and washed out to a certain degree. After initial swelling, this causes a subsequent drying-out of the skin, which may be further considerably intensified by washing-active additives.

In healthy skin, these processes are generally of no consequence since the protective mechanisms of the skin are able to readily compensate for such slight disturbances to the upper layers of the skin. However, even in the case of nonpathological deviations from the norm, e.g. as a result of wear damage or irritations caused by the environment,

photodamage, aging skin etc., the protective mechanism on the surface of the skin is impaired.

In aged skin, for example, regenerative renewal takes place at a slower rate, where, in particular, the water-binding capacity of the horny layer decreases. The skin thus becomes inflexible, dry and chapped ("physiologically" dry skin). Barrier damage is the result. The skin becomes susceptible to negative environmental effects, such as the invasion of micro-organisms, toxins and allergens. As a consequence, toxic or allergic skin reactions may even result.

In the case of pathologically dry and sensitive skin, barrier damage is present a priori. Epidermal intercellular lipids become obviously defective or are formed in an inadequate amount or composition. The consequence is increased permeability of the horny layer and inadequate protection of the skin against loss of hygroscopic substances and water.

The barrier effect of the skin can be quantified via the determination of the transepidermal water loss (TEWL). This is the evaporation of water from inside the body without taking into account the loss of water during perspiration. Determination of the TEWL value has proven to be extraordinarily informative and can be used to diagnose chapped or cracked skin, for determining the compatibility of surfactants which have very different chemical structures, and more besides.

For the beauty and well cared-for appearance of the skin, the proportion of water in the uppermost layer of the skin is of greatest significance. It can be favorably influenced within a limited scope by introducing moisture regulators.

Anionic surfactants, which are generally constituents of cleansing preparations, can lastingly increase the pH in the horny layer, which severely hinders regenerative processes which serve to restore and renew the barrier function of the skin. In this case, a new, frequently very unfavorable state of equilibrium is established in the horny layer between regeneration and the loss of essential substances as a result of regular extraction; this state has a decisive adverse effect on the outer appearance of the skin and the physiological mode of function of the horny layer.

For the purposes of the present invention, skin care is understood primarily as meaning that the natural function of the skin as a barrier against environmental influences (e.g. dirt, chemicals, microorganisms) and against the loss of substances endogenous to the body (e.g. water, lipids, electrolytes) is strengthened or restored.

Products for the care, treatment and cleansing of dry and stressed skin are known per se. However, their contribution to the regeneration of a physiologically intact, hydrated and smooth horny layer is limited with regard to extent and time.

The effect of ointments and creams on the barrier function and the hydration of the horny layer is based essentially on the coverage (occlusion) of the areas of skin treated. The ointment or cream represents, as it were, a (second) artificial barrier which is intended to prevent loss of water by the skin. It is equally easy to remove this physical barrier, for example using cleansers, again, as a result of which the original, impaired state is again achieved. Moreover, the skin care effect can decrease upon regular treatment. After use of the product is stopped, the skin reverts very quickly to the state prior to the start of treatment. In the case of certain products, the condition of the skin is even temporarily worsened in some circumstances. A permanent product effect is therefore generally not achieved or achieved only to a limited extent.

The effect of some pharmaceutical preparations on the barrier function of the skin consists even in selected damage to the barrier, which is intended to permit active ingredients to be able to penetrate into or through the skin into the body. Here, a disturbed appearance of the skin as a side effect is accepted to some extent as a small price to pay.

The effect of caring cleansing products consists essentially in an efficient refatting with sebum lipid-like substances. The simultaneous reduction in the surfactant content of such preparations permits a further limitation of the damage to the horny layer barrier.

However, the prior art lacks preparations which have a positive effect on the barrier function and hydration of the horny layer and enhance or even restore the physicochemical properties of the horny layer and, in particular, of the lamellae comprising intercellular lipids.

The object of the present invention was therefore to overcome the disadvantages of the prior art. In particular, skin care preparations and preparations for cleansing the skin were to be

made available which retain or restore the barrier properties of the skin, particularly when the natural regeneration of the skin is inadequate. They should also be suitable for the treatment and prophylaxis of secondary damage of the drying-out of skin, for example fissures or inflammatory or allergic processes, or also of neurodermatitis. It was also an object of the present invention to provide stable skin care cosmetic and/or dermatological compositions which protect the skin against environmental influences such as sun and wind. In particular, the effect of the preparations was to be physiological, rapid and long-lasting.

Surprisingly, and in a manner which could not have been foreseen by the person skilled in the art, these objects are achieved by

> cosmetic and dermatological preparations having an effective content of bile acids, their salts and/or their derivatives, it being possible for said active ingredients to be present either individually or as a mixture.

For the purposes of the present invention, "barrier strengthening" or "strengthening of the barrier function of the skin" is, in particular, to be understood as meaning the following effect: the active ingredients according to the invention interact with the lipids of the horny layer in a manner such that the arrangement of these lipids in the horny layer on a molecular plane is improved. This leads to the natural function of the skin as a barrier against environmental influences and against the loss of substances endogenous to the body being strengthened or restored.

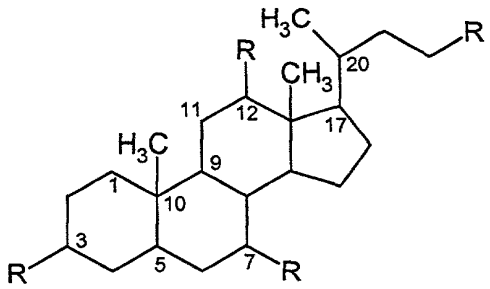
In every respect the preparations according to the invention are extremely satisfactory preparations. It had been unforeseen for the person skilled in the art that the preparations according to the invention

- better retain or restore the barrier properties of the skin,
- better counteract drying-out of the skin,
- better counteract skin aging and
- better protect the skin against environmental influences

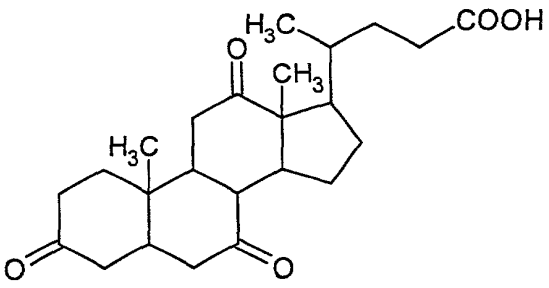
than the prior art preparations.

Bile is the exocrine secretion of the liver whose main constituents are water (86.7%), bile acids (9.1%), bile pigments (3%), cholesterol (0.3%), and fatty acids, proteins and inorganic substances. The function of the bile liquid within the framework of fat digestion consists in the emulsification of water-insoluble constituents of food in the intestine and in the

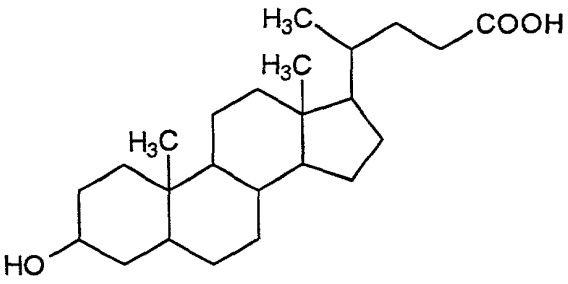
conversion of water-insoluble compounds to resorbable choleic acids. In addition, the bile acids, which occur in the bile as salts, keep the cholesterol in solution and facilitate its elimination. Bile acids are primarily substituted cholanic acids conjugated with glycine (glycocholic acid) or taurine (taurocholic acid), which have the following structural formula:



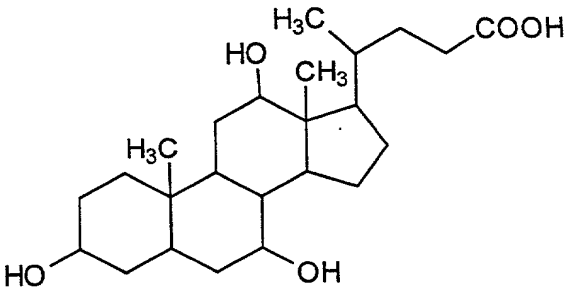
Advantageous for the purposes of the present invention are, for example, dehydrocholic acid, which is characterized by the following structure, and its salts:



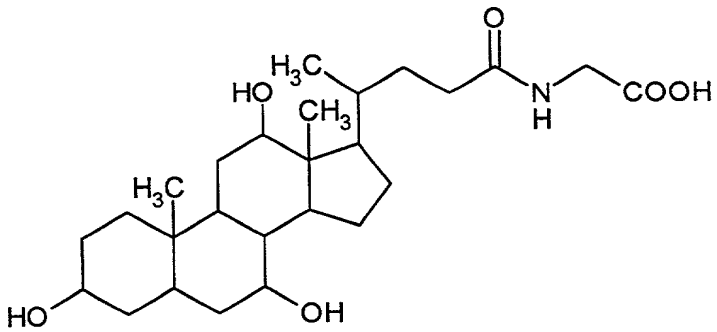
Also advantageous are lithocholic acid, which is characterized by the following structure, and its salts:



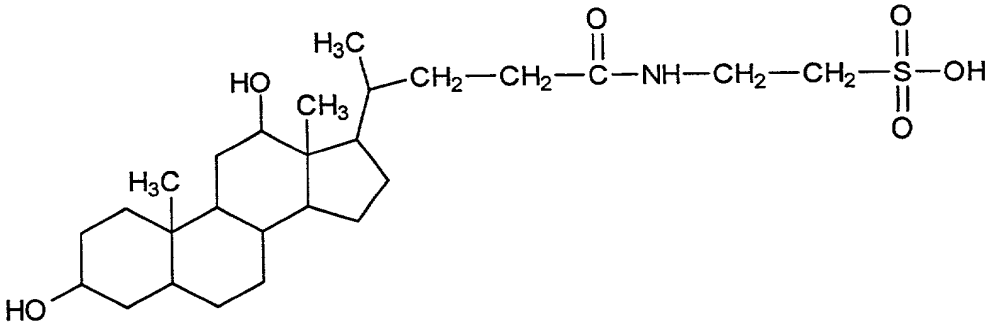
Also advantageous are cholic acid, which is characterized by the following structure, and its salts:



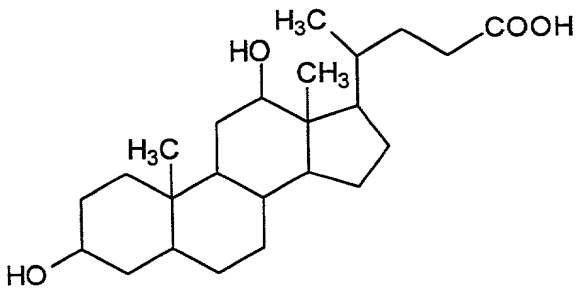
Also advantageous are glycocholic acid, which is characterized by the following structure, and its salts:



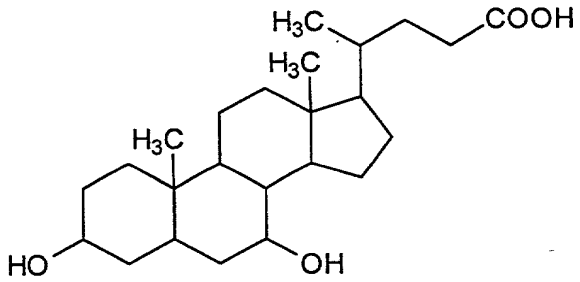
Also advantageous are taurolithocholic acid, which is characterized by the following structure, and its salts, in particular its sodium salt:



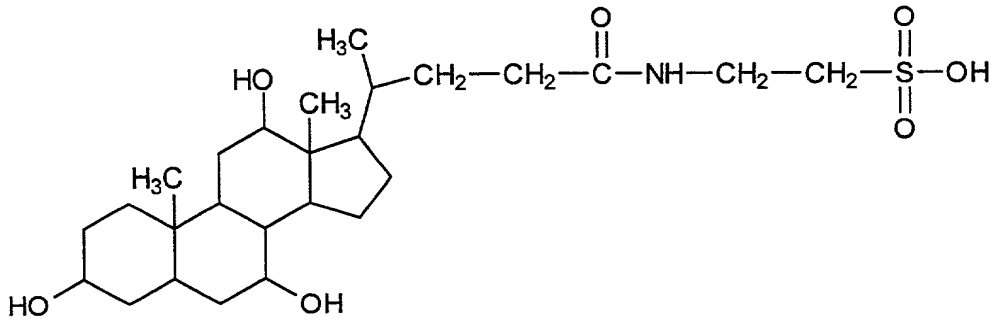
Particularly preferred for the purposes of the present invention are deoxycholic acid, which is characterized by the following structure, and its salts:



Also particularly preferred are ursodeoxycholic acid (chenodeoxycholic acid), which is characterized by the following structure, and its salts:



Also particularly preferred are taurocholic acid, which is characterized by the following structure, and its salts, in particular its sodium salt:



Also advantageous for the purposes of the present invention are the esters and ethers of the bile acids, in particular the esters and ethers of the aforementioned bile acids.

Bile acid ethers are obtainable by an etherification of at least one of the alcohol functions in position 3, 7 or 12 of the cholane ring. Particular preference is given to bile acid ethers obtainable by etherification of the alcohol function in position 3.

Advantageous for the purposes of the present invention are bile acid ethers obtainable by etherification with ethylene oxide, saturated and/or unsaturated, branched and/or unbranched alcohols having a chain length of from 2 to 22 carbon atoms.

Bile acid esters are obtainable by esterification of at least one of the alcohol functions in position 3, 7 or 12 of the cholane ring, and by esterification of the terminal acid functions. Advantageous for the purposes of the present invention are bile acid esters obtainable by esterification with saturated and/or unsaturated, branched and/or unbranched acids having a chain length of from 2 to 22 carbon atoms.

Also advantageous are bile acid esters obtainable by esterification of the terminal acid function with ethylene oxide, saturated and/or unsaturated, branched and/or unbranched alcohols having a chain length of from 2 to 22 carbon atoms.

Also advantageous for the purposes of the present invention are, in particular, the salts of the bile acids, in particular the alkali metal and/or alkaline earth metal salts, and the salts of mono- or divalent cations of elements from the transition groups, and also the lanthanides and/or actinides. Also advantageous are bile acid salts of ammonium ($-NH_3$), alkanolammonium derivatives having 2 to 9 carbon atoms in total, alkyl- or alkenyl-ammonium derivatives having 1 to 22 carbon atoms in total, pyridine, which may be substituted by an alkyl or alkenyl group which has 1 to 18 carbon atoms, and basic amino acids. According to the invention, particular preference is given to the sodium, potassium and/or triethanolamine salts of the bile acids.

The cosmetic or dermatological preparations or formulations according to the invention can have the customary composition and be used for the treatment, care and cleansing of the skin and/or of the hair and as a make-up product in decorative cosmetics. Accordingly, depending on their formulation, they may be used, for example, as skin protection cream, cleansing milk, sunscreen lotion, nourishing cream, day cream or night cream etc. It is optionally possible and advantageous to use the preparations according to the invention as a base for pharmaceutical formulations. The preparations according to the invention comprise, for example, 0.001 to 10% by weight, preferably 0.01% by weight to 1%, but in particular 0.01% by weight to 0.5% by weight, in each case based on the total weight of the preparations of the active ingredients according to the invention.
Also favorable are those cosmetic and dermatological preparations which are in the form of a sunscreen. In addition to one or more active ingredients according to the invention, these preferably comprise at least one UV-A filter substance and/or at least one UV-B filter substance and/or at least one inorganic pigment.

It is, however, also advantageous for the purposes of the present invention to provide cosmetic and dermatological preparations whose main purpose is not protection against sunlight, but which nevertheless comprise a content of UV protection substances. Thus, UV-A and UV-B filter substances are commonly incorporated into day creams, for example.

The cosmetic and dermatological preparations according to the invention may comprise cosmetic auxiliaries as are customarily used in such preparations, e.g. preservatives, bactericides, perfumes, antifoams, dyes, pigments which have a coloring action, thickeners, surface-active substances, emulsifiers, emollients, moisturizers and/or humectants, fats, oils, waxes and other customary constituents of a cosmetic or dermatological formulation, such as alcohols, polyols, polymers, foam stabilizers, electrolytes, organic solvents or silicone derivatives.

Depending on the type of product in each case, the amounts of cosmetic, dermatological or medicinal carrier substances and perfume to be used in each case can be readily determined by the person skilled in the art by simple exploratory experiments.

Preparations for the treatment and care of the skin are particularly preferred.

For use, the cosmetic and dermatological preparations according to the invention are applied to the skin and/or the hair in a sufficient amount in the manner customary for cosmetics.

Cosmetic and dermatological preparations according to the invention may exist in a variety of forms. Thus, for example, they may be a solution, an anhydrous preparation, an emulsion or microemulsion of the water-in-oil (W/O) type or of the oil-in-water (O/W) type, a multiple emulsion, for example of the water-in-oil-in-water (W/O/W) type, a gel, a solid stick, an ointment or also an aerosol. It is also advantageous to administer the active ingredients according to the invention in encapsulated form, e.g. in collagen matrices and other customary encapsulation materials, e.g. as cellulose encapsulations, in gelatin, wax matrices or liposomally encapsulated.

It is also possible and advantageous for the purposes of the present invention to incorporate the active ingredients according to the invention into aqueous systems or surfactant preparations for cleansing the skin and the hair.

In particular, the cosmetic and dermatological preparations according to the invention may also comprise antioxidants. According to the invention, favorable antioxidants which may be used are all the antioxidants which are suitable or customary for cosmetic and/or dermatological uses.

The antioxidants are advantageously chosen from the group consisting of amino acids (for example glycine, histidine, tyrosine, tryptophan) and derivatives thereof, imidazoles (for example urocanic acid) and derivatives thereof, peptides such as D,L-carnosine, D-carnosine, L-carnosine and derivatives thereof (for example anserine), carotenoids, carotenes (for example α-carotene, β-carotene, lycopene) and derivatives thereof, chlorogenic acid and derivatives thereof, lipoic acid and derivatives thereof (for example dihydrolipoic acid), aurothioglucose, propylthiouracil and other thiols (for example thioredoxin, glutathione, cysteine, cystine, cystamine and the glycosyl, N-acetyl, methyl, ethyl, propyl, amyl, butyl and lauryl, palmitoyl, oleyl, γ-linoleyl, cholesteryl and glyceryl esters thereof) and salts thereof, dilauryl thiodipropionate, distearyl thiodipropionate, thiodipropionic acid and derivatives thereof (esters, ethers, peptides, lipids, nucleotides, nucleosides and salts) and sulfoximine compounds (for example buthionine sulfoximines, homocysteine sulfoximine, buthionine sulfones, penta-, hexa- and hepta-thionine sulfoximine) in very low tolerated doses (for example pmol to μmol/kg), and furthermore (metal) chelating agents (for example α-hydroxy-fatty acids, palmitic acid, phytic acid, lactoferrin), α-hydroxy acids (for example citric acid, lactic acid, malic acid), humic acid, bile acid, bile extracts, bilirubin, biliverdin, EDTA, EGTA and derivatives thereof, unsaturated fatty acids and derivatives thereof (for example γ-linolenic acid, linoleic acid, oleic acid), folic acid and derivatives thereof, ubiquinone and ubiquinol and derivatives thereof, vitamin C and derivatives (for example ascorbyl palmitate, Mg ascorbyl phosphate, ascorbyl acetate), tocopherols and derivatives (for example vitamin E acetate), vitamin A and derivatives (vitamin A palmitate) and coniferyl benzoate of benzoin resin, rutic acid and derivatives thereof, α-glycosylrutin, ferulic acid, furfurylideneglucitol, carnosine, butylhydroxytoluene, butylhydroxyanisole, nordihydroguaiacic acid, nordihydroguaiaretic acid, trihydroxybutyrophenone, uric acid and derivatives thereof, mannose and derivatives thereof, zinc and derivatives thereof (for example ZnO, $ZnSO_4$), selenium and derivatives thereof (for example selenomethionine), stilbenes and derivatives thereof (for example stilbene oxide, trans-stilbene oxide) and the derivatives of these active ingredients mentioned which are suitable according to the invention (salts, esters, ethers, sugars, nucleotides, nucleosides, peptides and lipids).

The amount of the abovementioned antioxidants (one or more compounds) in the preparations according to the invention is preferably from 0.001 to 30% by weight, particularly preferably 0.05-20% by weight, in particular 1-10% by weight, based on the total weight of the preparation.

If vitamin E and/or derivatives thereof is or are the antioxidant or antioxidants, it is advantageous to choose the respective concentrations thereof from the range 0.001-10% by weight, based on the total weight of the formulation.

If vitamin A or vitamin A derivatives or carotenes or derivatives thereof is or are the antioxidant or antioxidants, it is advantageous to choose the respective concentrations thereof from the range 0.001-10% by weight, based on the total weight of the formulation.

The examples below serve to illustrate the present invention without limiting it. The numerical values in the examples are percentages by weight, based on the total weight of the respective preparations.

Example formulations:

1. Lecithin fluid

	% by wt.
Lecithin	5.00
Ursodeoxycholic acid	0.50
Cetearyl alcohol	1.00
Glycerol	3.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

2. Hydrodispersion gel

	% by wt.
Stearyl alcohol	2.00
Behenyl alcohol	2.00
Ceramide 3	0.20
Taurodeoxycholic acid	0.10
Carbopol	0.30
Hydroxyethylcellulose	0.40
Glycerol	3.00
Panthenol	1.00
Caprylic/capric triglyceride	3.00
Isopropyl palmitate	3.00
Shea butter	2.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes,	q.s.
Water	ad 100

3. Light gel

	% by wt.
Sucrose stearate	3.00
Cetearyl alcohol	2.00
Deoxycholic acid	0.02
Carbopol	0.50
Glycerol	3.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

4. O/W cream

	% by wt.
Sucrose stearate	4.00
Sucrose laurate	2.00
Taurolithocholic acid	0.02
Cetearyl alcohol	3.00
Glycerol	3.00
Dimethicone	2.00
Mineral oil	5.00
Isopropyl palmitate	3.00
Sunflower oil	3.00
Hydrogenated coconut fatty acid glyceride	2.50
Liquorice root extract	2.00
Carbomer	0.20
NaOH 45% strength	0.10
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

5. O/W lotion

	% by wt.
Stearic acid	1.50
Sorbitan monostearate	0.50
Ursodeoxycholic acid	0.05
Myristyl alcohol	1.00
Glycerol monostearate	0.50
Paraffin oil, subliquidum	10.00
Dimethicone	1.00
Octyldodecanol	2.00
Hydrogenated coconut fatty acid glyceride	0.50
Carbomer	0.10
Serine	0.50
Glycerol	5.00
Tocopherol acetate	0.50
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

6. W/O lotion

	% by wt.
PEG-7 hydrogenated castor oil	4.00
Glycocholic acid	0.01
Beeswax	3.00
Vaseline	4.00
Ozokerite	4.00
Paraffin oil, subliquidum	10.00
Glycerol	5.00
Octyl methoxycinnamate	2.50
Methylbenzylidenecamphor	2.50
Tocopherol acetate	1.00
Magnesium sulfate 7 H_2O	0.70
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

7. W/O cream

	% by wt.
PEG-7 hydrogenated castor oil	4.00
Wool wax alcohol	1.50
Deoxycholic acid	0.05
Vaseline	9.00
Ozokerite	4.00
Paraffin oil, subliquidum	10.00
Urea	10.00
Magnesiumsulfate 7 H_2O	0.70
Lactic acid	0.30
Sodium lactate	2.50
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

8. Silicone emulsion

	% by wt.
Dimethicone copolyol	2.00
Cyclomethicone	5.00
Dimethicone	3.0
Paraffin oil, subliquidum	8.00
Wheatgerm oil	4.0
Dehydrocholic acid	0.02
Glycerol	10.0
Sodium chloride	1.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

9. Ointment

	% by wt.
Vaseline	36.00
Ceresine	10.00
Zinc oxide	4.00
Wheatgerm oil	20.00
Taurocholic acid	0.02
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Paraffin oil	ad 100

10. Skin oil

	% by wt.
Cetyl palmitate	3.00
C_{12-15} Alkyl benzoate	2.00
Polyisobutene	10.00
Squalane	2.00
Ursodeoxycholic acid	0.05
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Paraffin oil	ad 100

11. Bath oil

	% by wt.
Paraffin oil	20.00
PEG-40 hydrogenated castor oil	5.00
Deoxycholic acid	0.50
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Soybean oil	ad 100

12. Lip care stick

	% by wt.
Caprylic/capric triglyceride	25.00
Octyldodecanol	25.00
Ceramide 3	0.50
Ursodeoxycholic acid	0.20
Beeswax	20.00
Cetyl palmitate	8.00
Jojoba oil	5.00
Carnauba wax	4.00
Tocopherol acetate	0.75
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Squalane	ad 100

13. Emulsion lip care stick

	% by wt.
Caprylic/capric triglyceride	30.00
Octyldodecanol	20.00
Polyglyceryl-3 dioleate	3.50
Beeswax	10.00
Dehydrocholic acid	0.10
C_{20-40} Alkyl stearate	5.00
Jojoba oil	5.00
Carnauba wax	2.00
Tocopherol acetate	0.75
Water	5.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Squalane	ad 100

14. Lipstick

	% by wt.
Caprylic/capric triglyceride	22.00
Octyldodecanol	22.00
Ursodeoxycholic acid	0.20
PEG-5 soya sterol	0.50
Beeswax hydrolysate	5.00
Beeswax	15.00
Cetyl palmitate	2.00
Jojoba oil	5.00
Carnauba wax	2.00
Tocopherol acetate	0.75
Color pigments, color lakes, titanium dioxide	q.s.
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Squalane	ad 100

15. Emulsion foundation

	% by wt.
Sorbitan monostearate	1.50
Sorbitan monooleate	1.00
Glycerol monostearate	1.00
Taurocholic acid	0.20
Glyceryl lanolate	1.00
Paraffin oil, subliquidum	7.00
Octyldodecanol	7.00
Hydrogenated coconut fatty acid glyceride	4.00
Octyl methoxycinnamate	2.00
Butylmethoxydibenzoylmethane	1.00
Carbomer	0.10
Glycerol	5.00
1,3-Butylene glycol	2.00
Tocopherol acetate	1.00
Sodium octenyl succinate starch (Amiogum® from American Maize-Products Company / CERSTAR)	2.50
Magnesium silicate	1.00
Mica	1.00
Iron oxide	1.00
Titanium dioxide	2.50
Talc	5.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

16. Haircare composition

	% by wt.
TEA - Cocoyl hydrolyzed collagen	30.00
Monoethanolamine lauryl sulfate	25.00
Almond oil	2.00
PEG-25 soya sterol	2.00
Deoxycholic acid	0.20
Sodium chloride	1.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

17. Care shampoo

	% by wt.
Sodium lauryl sulfate	34.00
Disodium lauryl sulfosuccinate	6.00
Cocoamidopropylbetaine	10.00
Lithocholic acid	0.02
Glycol distearate	5.00
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

18. Pump spray

	% by wt.
PEG-40 hydrogenated castor oil	2.00
Glycerol	1.00
PEG-25 soja sterol	2.00
Glycocholic acid	0.02
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

19. Roll-on emulsion

	% by wt.
Tricetеareth phosphate	0.30
Octyldodecanol	2.00
C_{12-15} Alkyl benzoate	2.00
C_{10-30} Alkyl acrylate	0.15
Taurolithocholic acid	0.05
Antioxidants, preservatives, neutralizing agents, perfume, dyes	q.s.
Water	ad 100

Patent claims:

1. A cosmetic and dermatological preparation with an effective content of bile acids, their salts and/or their derivatives, it being possible for said active ingredients to be present either individually or as a mixture.

2. The preparation as claimed in claim 1, wherein cosmetic or dermatological auxiliaries, additives and/or active ingredients are additionally present.

3. The preparation as claimed in any of the preceding claims, wherein the content of one or more bile acids, their salts and/or their derivatives in the cosmetic or dermatological preparations is chosen from the range 0.001 to 10% by weight, preferably 0.01% by weight to 1% by weight, but in particular 0.01% by weight to 0.5% by weight, in each case based on the total weight of the preparations.

4. The preparation as claimed in any of the preceding claims, wherein the active ingredient(s) is/are chosen from the group consisting of deoxycholic acid, ursodeoxycholic acid, taurocholic acid and/or salts thereof and/or derivatives thereof.

5. The preparation as claimed in any of the preceding claims, wherein the active ingredient(s) is/are chosen from the group of esters and ethers of bile acids.

6. The preparation as claimed in any of the preceding claims, wherein the active ingredient(s) is/are chosen from the group of salts of bile acids, in particular the alkali metal and alkaline earth metal salts, the salts of mono- or divalent cations of elements from the transition groups, and also the lanthanides and actinides, of salts of ammonium ($-NH_3$), alkanolammonium derivatives having 2 to 9 carbon atoms in total, alkyl- and alkenylammonium derivatives having 1 to 22 carbon atoms in total, pyridine, which may be substituted by an alkyl or alkenyl group which has 1 to 18 carbon atoms, and of salts of basic amino acids.

7. The use of preparations as claimed in any of claims 1 to 6 for strengthening the barrier function of the skin.

Abstract:

Cosmetic and dermatological preparations having an effective content of bile acids, their salts and/or their derivatives, it being possible for said active ingredients to be present either individually or as a mixture.

ATTORNEY DOCKET No.: xxxx

COMBINATION DECLARATION & POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

COSMETIC AND DERMATOLOGICAL PREPARATIONS HAVING AN EFFECTIVE CONTENT OF BILE ACIDS, THEIR SALTS AND/OR THEIR DERIVATIVES

the specification of which was filed on January 24, 2001

as Application Serial No. 09/744,506 and

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed
198 34 814.2 (Number)	Germany (Country)	01.08.1998 (Day/Month/Yr. Filed)	x yes __ no
_____ (Number)	_____ (Country)	_____ (Day/Month/Yr. Filed)	__ yes __ no

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/EP99/05157 (Application Serial No.)	July 20, 1999 (Filing Date)	(Status) (patented,pending,abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented,pending,abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punished by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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